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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MERTZ, PREMA MARIA

ART UNIT

PAPER NUMBER

1646

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,388	Applicant(s) ROSS ET AL.	
	Examiner Prema M. Mertz	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/10/09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 13-15 is/are pending in the application.
- 4a) Of the above claim(s) 4,5 and 13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 2, 4-5, 7-12, 16-18 have been canceled in the amendment filed 4/10/09 and claims 19-42 have been canceled previously. Amended claim 1 (4/10/09) and previously presented claims 3 and 6 are under consideration by the Examiner.

2. Receipt of applicant's arguments and amendments filed on 4/10/2009 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 4/10/2009:

- (i) the objection to the specification;
- (ii) the rejection of claim 1, under 35 U.S.C. 101;
- (iii) the rejection of claims 1-3, 6-9, 11-12, 16-18, under 35 U.S.C. 112, second paragraph;

Applicant's arguments with respect to claims 1, 3, 6, have been considered but are moot in view of the new ground(s) of rejection.

- (iv) the rejection of claims 1-2, 7-9, 11-12 under 35 U.S.C. 102(b) as being anticipated by Benting (1999).

4. Applicant's arguments filed on 4/10/09 have been fully considered and were persuasive in part. The issues remaining and new issues are stated below.

Claim Rejections - 35 USC § 112, first paragraph, written description

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 1, 3, 6, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons of record set forth at pages 4-6 of the previous Office action of 12/5/2007.

Applicants argue that claim 1 has been amended to recite:

“A polypeptide comprising a domain that directs the attachment of a glycosylphosphatidylinositol molecule, wherein said polypeptide comprises a modified human growth hormone polypeptide wherein said modification is substitution of glycine 120 with arginine of the amino acid sequence SEQ ID NO: 24.”

However, contrary to Applicants arguments, support for only a domain comprising the amino acid sequence set forth in SEQ ID NO:12, 13, and 14 has been provided in the instant specification. Moreover, no disclosure, beyond the mere mention of other domains is made in the specification. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicants were not in possession of the claimed genus of polypeptides. This is insufficient to support the generic

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claims as provided by the Interim Written Description Guidelines published in the June 15, 1998, Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only the polypeptide comprising the domains comprising the amino acid sequences set forth in SEQ ID NO:12, 13 and 14, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 112, first paragraph, scope of enablement

5b. Claims 1, 3, 6, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprising a domain of amino acid sequence set forth in SEQ ID NO:12 that directs the attachment of a glycosylphosphatidylinositol molecule, said polypeptide comprising a substitution of glycine 120 with arginine in the amino acid sequence set forth in SEQ ID O:24, does not reasonably provide enablement for a polypeptide as set forth in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

This rejection is maintained for reasons of record set forth at pages 7-9 of the previous Office action of 12/5/2007.

Applicants argue that claim 1 has been amended to recite:

“A polypeptide comprising a domain that directs the attachment of a glycosylphosphatidylinositol molecule, wherein said polypeptide comprises a modified human

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growth hormone polypeptide wherein said modification is substitution of glycine 120 with arginine of the amino acid sequence SEQ ID NO: 24.”

However, contrary to Applicants arguments, the specification, page 4, [0012-0014], discloses that:

“**In a further preferred embodiment** of the invention said domain comprises the amino acid sequence:

PSPTPTETAT PSPTPKPTST PEETEAPSSA TTLISPLSLI VIFISFVLLI

(SEQ ID NO: 12).

In an alternative preferred embodiment of the invention said domain comprises the amino acid sequence:

LVPRGSIEGR GTS 1TAYNSE GESAEFFFL ILLLLVLV (SEQ ID NO: 13).

In a further alternative preferred embodiment of the invention said domain comprises the amino acid sequence:

TSITAYKSE GESAEFFFL ILLLLVLV (SEQ ID NO: 14). “

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Furthermore, except for the domain sequences set forth in SEQ ID NO:12, 13, and 14, the claims fail to recite any other sequence limitations, and thus the skilled artisan would have to resort to trial and error experimentation to identify other domains meeting the limitations of the claims.

The recitation of the domains on page 4 of the specification are “exemplary” and include other known domain peptides as well as domain peptides yet to be discovered.

An application must be complete as filed. The instant specification as filed does not provide any guidance or examples that would enable a skilled artisan to make and use another domain as claimed.

Applicants are reminded that “Argument of counsel cannot take the place of evidence lacking in the record” (*In re Scarbrough*, 182 USPQ 298, 302 (CCPA 1974)).

Claim Rejections - 35 USC § 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 6, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, lines 3-4, recites the limitation "wherein said modification is substitution....". There is insufficient antecedent basis for this limitation in the claim. It is suggested that the claim be amended to recite “....comprising a substitution...”.

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Claim 1, lines 4-5, is unclear because it recites “.....substitution of glycine 120 with arginine of the amino acid sequence SEQ ID NO:24” rather than the correct “.....substitution of glycine 120 with arginine in the amino acid sequence set forth in SEQ ID NO:24”.

Similarly, claim 3, line 2, is unclear and recites “comprises the amino acid sequence SEQ ID NO:12” rather than the correct “comprises the amino acid sequence set forth in SEQ ID NO:12”.

Claim 6 is rejected as vague and indefinite insofar as it depends on claim 1 for its limitations.

Conclusion

No claim is allowed.

Claims 1, 3, 6, are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Prema Mertz/
Prema Mertz, Ph.D., J.D.
Primary Examiner
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